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In re Application of:

CEZANNE et al.
Serial No: 10/582,850
Filed: June 14, 2006
Attorney Docket No: MERCK-3185

DECISION
ON
PETITION

This letter is in response to the Petition under 37 C.F.R. 1.144 filed on December 29, 2008.

BACKGROUND

This application was filed as a national stage application in compliance with under 35 U.S.C. 371 and as such is subject to PCT unity of invention practice.

On February 6, 2008 a restriction requirement was mailed to applicant setting forth 11 groups and requiring an election of species. The examiner referred to the "Markush" practice guidelines and argued that a common core was not present. In addition, the examiner asserted that a preliminary search of the core yielded numerous iterations and that thus a common special technical feature was not present.

In the paper filed March 28, 2008 applicant elected Group I (claims 1-5 & 7-29) and stated that claims 1-37 read on the elected group. Applicant elected the species (R)-1-(4-chlorophenyl)-3-[2-(1'-methyl-4,4'-bipiridinyl-1-yl)-2-oxo-1-phenylethyl]urea. Applicant's traversal stated:

The compounds share a common activity or property as discussed in applicants' specification. Additional, the alternatives will share a common significant structure,

namely a central piperidinyl ring, when Z, Z' and E form a piperidine ring. Thus, applicants respectfully request that groups III, IV, and IX (as well as any relevant compounds within group XI) be examined with the elected Group I as to those compounds in which Z, Z' and E form a piperidine ring.

Applicant additionally amended claims 23-29 to be method of use of the compounds of claim 1 and introduced new claims 30-37 directed to two subgeneruses of claim 1.

In the Office Action of May 21, 2008 the examiner responded to applicant's traversal as follows:

This is not found persuasive because when fairly considered, there is not seen a significant common core for compounds of groups I-XI. In group I, a combination of variables Z, Z', and E form a piperidine ring. In group II, a combination of variables Z, Z', and E form a piperazine ring. In addition, each of these groups differs by variable T. Variable T is piperidine in group I and phenyl in group II. A search for these two groups cannot be considered co-extensive.

The examiner made no comment as to whether or not the amendments to claims 23-29 presented an invention having unity of invention with the elected group nor did he address whether claims 30-37 had unity of invention with the elected group.

Applicant's response of June 25, 2008 reiterated the arguments presented in response to the original restriction requirement.

Applicant filed the instant petition December 29, 2008 which essentially reiterates his previous arguments and additionally presents arguments relating to MPEP §803.02 with emphasis on *In re Harnish* (206 USPQ 300 (CCPA 1980)) and *Ex parte Hozumi* (3 USPQ2d (Bd.Pat.App. & Int. 1984)).

DISCUSSION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims.

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.

If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered.

PCT/GL/ISPE/1 Chapter 10 Unity of Invention provides examples regarding unity of invention when a Markush group is claimed. 10.44 Example 24 appears particularly relevant to the instant claims.

Claim 1: A pharmaceutical compound of the formula:

A – B – C – D – E

wherein:

A is selected from C₁-C₁₀ alkyl or alkenyl or cycloalkyl, substituted or unsubstituted aryl or C₅-C₇ heterocycle having 1-3 heteroatoms selected from O and N;

B is selected from C₁-C₆ alkyl or alkenyl or alkynyl, amino, sulfoxyl, C₃-C₈ ether or thioether;

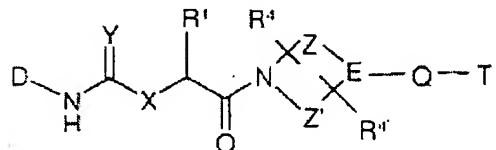
C is selected from C₅-C₈ saturated or unsaturated heterocycle having 1-4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

D is selected from B or a C₄-C₈ carboxylic acid ester or amide; and

E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl, pyridyl, or oxazolyl.

From the above formula no significant structural element can be readily ascertained and thus no special technical feature can be determined. Lack of unity exists between all of the various combinations. The first claimed invention would be considered to encompass the first mentioned structure for each variable, that is, A is C₁ alkyl, B is C₁ alkyl, C is a C₅ saturated heterocycle having one O heteroatom, D is C₁ alkyl, and E is a substituted phenyl.

Claim 1 as originally presented recites the following structure:

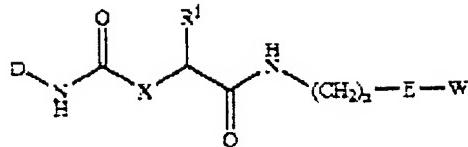


In order that claim 1 has unity of invention it must have a special technical feature which is a contribution over the prior according to PCT Rule 13. The examiner presented search evidence that structures within the scope of claim 1 were known in the prior art, however, no actual prior art was cited.

Given that claim 1 lacked unity of invention the examiner must then consider whether the dependent claims possess unity of invention. This presents significant difficulties with respect to claims 1-21 as they directly depend from claim 1 and define different subgenera. However, such an analysis is incumbent on the examiner.

The examiner set forth groups, one of which is a catchall group, based on the Markush practice analysis suggested for applications filed under §371. Such an analysis should have followed the guidance of Example 24 cited above and should have included the dependent claims. The end result of such an analysis would have been a holding of lack of unity potentially resulting in thousands of groups.

US 20040038858, which was of record at the time of the restriction requirement, is the English equivalent of WO 02/48099 and has four inventors in common with the instant application and sets forth the following:



[0002] in which

[0003] D is phenyl or pyridyl, each of which is unsubstituted or monosubstituted or polysubstituted by Hal, A, OR², N(R²)₂, NO₂, CN, COOR² or CON(R²)₂,

[0004] R¹ is H, Ar, Het, cycloalkyl or A, which may be substituted by OR², SR², N(R²)₂, Ar, Het, cycloalkyl, CN, COOR² or CON(R²)₂,

[0005] R² is H or A,

[0006] E is phenylene, which may be monosubstituted or polysubstituted by Hal, A, OR², N(R²)₂, NO₂, CN, COOR² or CON(R²)₂, or is piperidine-1,4-diyil,

[0007] W is Ar, Het or N(R²)₂ and, if E=piperidine-1,4-diyil, is alternatively R² or cycloalkyl,

[0008] X is NH or O,

[0009] A is unbranched or branched alkyl having 1-10 carbon atoms, in which one or two CH₂ groups may be replaced by O or S atoms and/or by —CH=CH— groups and/or in addition 1-7 H atoms may be replaced by F,

[0010] Ar is phenyl which is unsubstituted or monosubstituted, disubstituted or trisubstituted by Hal, A, OR², N(R²)₂, NO₂, CN, COOR², CON(R²)₂, NR²COA, NR²SO₂A, COR², SO₂NR², SO₃H or S(O)_mA,

[0011] Het is a monocyclic or bicyclic, saturated, unsaturated or aromatic heterocyclic radical having from 1 to 4 N, O and/or S atoms, which may be unsubstituted or monosubstituted, disubstituted or trisubstituted by Hal, A, OR², N(R²)₂, NO₂, CN, COOR², CON(R²)₂, NR²COA, NR²SO₂A, COR², SO₂NR², SO₃H, S(O)_mA and/or carbonyl oxygen,

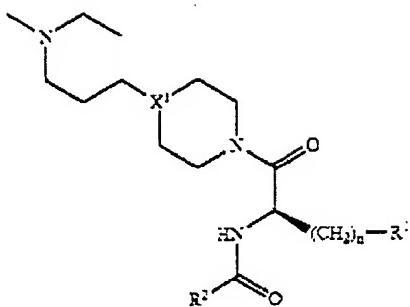
[0012] Hal is F, Cl, Br or I,

[0013] n is 0 or 1,

[0014] m is 0, 1 or 2.

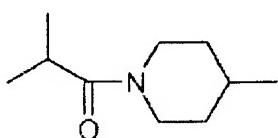
The compounds described above are a subgenus of the compounds presented in claim 1 of the instant application. In particular, the combination of (E, W) in the '858 publication is a subgenus of T of the instant application when n=0.

WO 03/050199 sets forth the following structure:



The compounds within the scope of the genus in '199 differ appear to fall within the scope of claim 1 of the instant application because (CH₂)_n-R¹ is a subgenus of A of instant claim 1 when A contains 3 carbons and is substituted by 3 fluorines.

Applicant has argued that there is a central core which is



However, WO 03/050199 teaches such a core which means that the core does not constitute a special technical feature which would link Groups III, IV and IX.

The examiner's remarks concerning search burden are not consonant with Lack of Unity practice.

The examiner's requirement for an election of species and the remarks attendant thereto are confusing. MPEP §1893.03(d) provides guidance with respect to lack of unity and in particular references form paragraph ¶18.20. Claim 22 is the sole claim in which species are recited and the examiner has provided no explanation as to why the species of claim 22 lack unity of invention nor which broader claims embrace them.

Applicant's arguments with regard to MPEP §803.02 with emphasis on *In re Harnish* (206 USPQ 300 (CCPA 1980)) and *Ex parte Hozumi* (3 USPQ2d (Bd.Pat.App. & Int. 1984)) relate to applications not filed under the provisions of 35 USC §371. To the extant that said arguments apply to cases filed under §371 the arguments are not persuasive as they are predicated on the presence of a common core which would confer unity of invention. But it is clear from the art

discussed above that the common core was known in the art and thus cannot confer unity of invention.

DECISION

Applicant's originally filed claims do not possess unity of invention as there is prior art teaching species within the scope of applicant's claims-claim 21 is excepted. Based on the prosecution of the application at least the first species recited in claim 21 appears free of the prior art. However, it is unresolved whether all the species within claim 21 share a common core which is a contribution over the prior art.

Thus, upon the resumption of prosecution the examiner needs to determine if the species recited within claim 21 share a common core and to further establish the relationship of the species of claim 21 to claims 1-20 as well as claims 30-37.

Following his determination the examiner is to either set forth a new restriction requirement or withdraw the requirement altogether.

The petition is GRANTED for the reasons set forth above.

Should there be any questions about this decision, please contact Quality Assurance Specialist Michael P. Woodward, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-8373 or by facsimile sent to the general Office facsimile number, 571-273-8300.



Remy Yucel
Director, Technology Center 1600